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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,862	07/12/99	THORPE	P 4001.002282

HM22/0921

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EXAMINER	
HELMS,L	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 09/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/351,862	Thorpe et al
Examiner	**Group Art Unit**
Larry R. Helms Ph.D.	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *NONE* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-38* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION.

1. Upon cursory review, Claim 1 in the instant application has been written to encompass several inventions and contains language that does not allow for proper restriction. For example, it is unclear what is meant by the phrase "a first antibody" when the claim does not require a "second antibody". In addition, the phrase "second agent" is not clear because there is no "first agent" recited in the claim. A similar case is seen for independent claim 34. Independent claim 37 recites a "first agent" which is unclear if this is different from the "second agent" recited in claim 1. Moreover, the agent recited in the claim could be among a plethora of compounds, such as antibodies, DNA, or chemical compounds, just to name a few. The agent recited in claim 1 has been improperly defined in functional terms rather than in properly restricted terms based on structure. Claim 38 is not clearly written and properly restrict able because the language of the claim "in combination" can encompass a method, a product, , a kit, a composition, a method of combining, etc.. It is not clear to what type of statutory invention claim 38 belongs.

In addition, it is pointed out that applicants have presented the instant claims in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct antibodies that bind to distinct antigens of phosphatidylethanolamine or phosphatidylserine to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth

for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species.

Upon election, applicant is required to point to which agent read upon the elected invention.

To allow Applicant an opportunity to correct these errors, Applicant is invited to respond to this preliminary Restriction Requirement addressing only independent claims 1, 31, 34, and 37 (38 was not included because of reasons above) and to amend the claims to address the various issues raised above. NOTE: For the Restriction Requirement the anti-cancer agent will be interpreted to be an antibody.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 and 31, in part, drawn to a kit comprising an antibody that binds to PE and a detectably-labeled antibody, classified in class 530, subclass 388.9.

   II. Claims 1 and 31, in part , drawn to a kit comprising an antibody that binds to PS and a detectably-labeled antibody, classified in class 530, subclass 388.9.

   III. Claims 1, 34, and 37, in part, drawn to a kit comprising an antibody that binds to PE and an anti-cancer antibody, classified in class 530, subclass 388.9.

   IV. Claims 1, 34, and 37, in part, drawn to a kit comprising an antibody that binds to PS and an anti-cancer antibody, classified in class 530, subclass 388.9.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV represent separate and distinct products which structurally and functionally distinct. The kit of Group I comprises an antibody which binds to PE compared to Group II which comprises an antibody specific for PS. The kit of Group III comprises an antibody to PE and an anti-cancer antibody compared to the kit of Group IV which comprises an antibody to PS and an anti-cancer antibody. The kits of Groups I-II differ from those of Groups III-IV because Groups I-II do not contain an anti-cancer antibody, while Groups I-II comprise a kit with a labeled antibody.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a

general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

JULIE BURKE
PRIMARY EXAMINER